

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P023523WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB99/03979	International filing date (day/month/year) 29/11/1999	Priority date (day/month/year) 27/11/1998
International Patent Classification (IPC) or national classification and IPC C12N15/62		
Applicant CELLTECH THERAPEUTICS LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 26/06/2000	Date of completion of this report 22.02.2001
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- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-7
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-7
Industrial applicability (IA)	Yes:	Claims	1-7
	No:	Claims	

- 2. Citations and explanations**
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

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Re Item V

1. The documents mentioned in this written opinion are numbered as in the International Search Report (ISR), i.e. D1 corresponds to the first document of the ISR etc.

2. As the priority document for the application was not available at the time of drafting of the present written opinion, it is established under the assumption that the entire subject-matter is entitled to the claimed priority. If this is not the case, the 'P' document cited in the search report may have to be considered for novelty and/or inventive step. This document (published by the inventors) would be detrimental to most, if not all, of the claimed subject-matter (Article 33(2), (3) PCT).

3. The present application does not satisfy the criterion set forth in Article 33(3) PCT because the subject-matter of **claims 1-7** does not involve an inventive step. D1 is considered to represent the closest prior art and discloses the determination of a specifically cleavable by copper (II) ions.

The difference between D1 and the subject matter of **claims 1-7** of the present application is the use of this site for the creation of an DNA encoding a hybrid protein, which can be cleaved after expression vector.

Starting from D1, the underlying technical problem is the provision of a DNA which expresses cleavable fusion proteins, which are specifically cleaved by copper II ion.

The subject-matter of the claims referred to above is considered to solve this problem. However, the solution proposed in **claims 1-7** of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

DNA expressing hybrid proteins, which can be cleaved by specific proteases are well known in the prior art see for example D3, which discloses the use of the coagulation factor X sequence specific site (D3, Abstract). Thus a skilled person would try also use the teaching of D1 in order to solve the above formulated problem. Consequently, **claims 1-7** do not fulfil the requirements of Article 33(3) PCT.

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Re Item VIII

4. A DNA sequence encoding a protein (see e.g. **claim 1**) - being a chemical product - has to be characterised e.g. by its sequence or as a product by process, but not merely by its function. According to the PCT-Guidelines C III 4.7. and 4.7.a, the area defined by the claims must be as precise as the invention allows. That means that claims which attempt to define the invention, or a feature thereof, by a result to be achieved, should not be allowed.